

## **REMARKS**

### **STATUS OF THE CLAIMS**

Claims 1-9, 11-20 and 22-29 are presently pending. Claims 1, 11-13, 15, 17, 20, 22 and 24 have been amended. Claims 10 and 21 are cancelled. Claim 1 has been amended to describe a more particular embodiment of the invention; support for the changes to Claim 1 may be found in the specification, for example, page 2 paragraph 12. Claims 11-13, 15, 17, 20, 22 and 24 have been amended to change the dependency from cancelled Claim 10 to Claim 1. Claim 10 has been cancelled as now being included in Claim 1. Thus, Claims 1-9, 11-20 and 22-29 are currently under examination.

### **WITHDRAWAL OF CERTAIN PREVIOUS REJECTIONS**

The Examiner's withdrawal of certain previous rejections is noted with thanks and the remaining rejections are those discussed below.

### **INFORMATION DISCLOSURE STATEMENT**

It is noted that the Applicant is endeavoring to obtain the information for selected references listed on the IDS that have not yet been considered due to unspecified dates. A supplemental communication will be submitted after this information has been obtained.

### **REJECTION UNDER 35 U.S.C. §103(a)**

The Examiner rejects Claims 1-7, 9-20 and 22-26 under 35 U.S.C. §103(a) as being unpatentable over Pinchuk et al. (U.S. Pub. No. 2002/0107330 A1) ("PINCHUK") in view of Schwarz (U.S. Application Publication. No. 2003/0236514) ("SCHWARZ"). This rejection is respectfully traversed.

It is believed that the Examiner has not met his burden of establishing a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the

claimed features. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Also, according to the MPEP in a discussion under Section 2141:

[T]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at \_\_\_, 82 USPQ2d at 1396.

The invention as currently claimed is directed to an implantable or insertable medical device comprising (a) a therapeutic agent and (b) a polymeric release region that controls the release of said therapeutic agent upon administration to a patient, said polymeric release region comprising an acrylic graft copolymer which is a block copolymer comprising (i) a rubbery block of rubbery acrylic units and (ii) a hard block of hard units.

PINCHUK teaches a composition for delivery of a therapeutic agent comprising: (a) a biocompatible block copolymer comprising one or more elastomeric blocks and one or more thermoplastic blocks and (b) a therapeutic agent, wherein the block copolymer is loaded with the therapeutic agent; and a medical device comprising (a) the biocompatible block copolymer and (b) a therapeutic agent, wherein the block copolymer is loaded with the therapeutic agent. The Examples of PINCHUK are limited to polystyrene-polyisobutylene-polystyrene copolymer. As noted by the Examiner, there is no teaching or disclosure in PINCHUK of graft copolymers. Further, there is no suggestion that an acrylic graft copolymer should be used.

The Examiner tries to combine SCHWARZ with PINCHUK in order to fill in the concept of graft copolymers. This rejection must also fail. SCHWARZ teaches medical devices that provide controlled release of a therapeutic agent using a release layer comprising a maleic anhydride polymer selected from maleic anhydride copolymers and maleic anhydride graft polymers. The Figures in

SCHWARZ are more limited and are all based on random copolymers of styrene and maleic anhydride. SCHWARZ is limited to maleic anhydride copolymers and maleic anhydride graft polymers. There is no teaching or suggestion in SCHWARZ that would lead one to use acrylic graft copolymers of the type described in the invention. Even if SCHWARZ and PINCHUK were combined, it would result in using only maleic anhydride copolymers, not maleic anhydride graft polymers.

The Examiner tries to support the rejection based on the combination of PINCHUK and SCHWARZ by stating that the motivation for doing so would be to increase the flexibility of a stent (as an example of a medical device). This logic must fail. There is no teaching or discussion in either PINCHUK or SCHWARZ about the importance of flexibility. PINCHUK discusses the concept of tensile strength (see paragraph 42), especially since both devices and coatings are included as possible embodiments. SCHWARZ discusses the concepts of strength (in general) and diffusion properties (see paragraph 53), stretchability (see paragraph 62), and release characteristics (see paragraphs 70-71). The focus of SCHWARZ is on the release rate of the therapeutic agent from the coatings containing the maleic anhydride polymer not the flexibility of the maleic anhydride polymer.

Additionally, any general concept of graft copolymers without consideration of the chemical types and properties of such graft copolymers is merely hindsight reconstruction and does not result in the claimed invention with the specific acrylic graft copolymer which is a block copolymer comprising (i) a rubbery block of rubbery acrylic units and (ii) a hard block of hard units. As noted above, rejections based on obviousness cannot be sustained by mere conclusory statements and there must be some articulated reasoning with a rational foundation to support any legal conclusion of obviousness.

Claim 8 is rejected under 35 U.S.C. §103(a) as being unpatentable over PINCHUK in combination with SCHWARZ taken in view of Van Dijk et al. (PCT Application Publication. No. WO/2000/061203) ("VAN DIJK"). This rejection is traversed for the reasons previously discussed above for PINCHUK in combination with SCHWARZ. Additionally, the relevance of VAN DIJK is not understood since the device in VAN DIJK is metallic in composition. The

current invention, including Claim 8, does not recite any metallic component and the comparison of an elongation value of a metal to the elongation value of a polymeric material is not relevant to patentability.

Claim 27 is rejected under 35 U.S.C. §103(a) as being unpatentable over PINCHUK in combination with SCHWARZ taken in view of Ding et al. (U.S. Pat. No. 5,837,313) (“DING”), with DING being cited merely for the concept of sterilization. This rejection is traversed for the reasons discussed above for PINCHUK in combination with SCHWARZ. This rejection is further traversed since DING et al comprises a coating composition of polymeric silicone and does not relate to any of the compositions used in PINCHUK, SCHWARZ or the present invention, especially since the present invention uses specific acrylic graft copolymer which is a block copolymer comprising (i) a rubbery block of rubbery acrylic units and (ii) a hard block of hard units.

Since there is no combination of references that teach or suggest each and every element of the claimed invention, withdrawal of the rejections of Claims 1-7, 9-20 and 22-26 (noting the cancellation of Claim 10 for other reasons) based on 35 U.S.C. §103(a) is requested.

#### **REJECTION UNDER 35 U.S.C. §102(a)**

The Examiner states that the rejection previously made under 35 U.S.C. §102(e) on the basis of PINCHUK is now being converted to a rejection under 35 U.S.C. §102(a). It is assumed that the Examiner also intends to refer to Claims 1-7, 9-20 and 22-26 for this rejection. This rejection is also traversed.

For a reference to anticipate a claim it must disclose each and every element of the claim. See MPEP 2131 and cases cited therein, especially *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989) (“The identical invention must be shown in as complete detail as is contained in the ... claim.”) See also *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990). (The elements must be arranged as required by the claim, but this is not an *ipse dixit* test, i.e., identity of terminology is not required.)

Since PINCHUK does not teach each and every element of the claimed invention, particularly the use of a graft copolymer, this rejection must fail.

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## **CONCLUSION**

In view of the foregoing, it is believed that Claims 1-7, 9, 11-20 and 22-26 are now in condition for allowance. Reconsideration of the case and a Notice of Allowability are requested. If the Examiner believes there are still unresolved issues, a telephone call to the undersigned would be welcomed.

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Respectfully submitted,

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